

REMARKS/ARGUMENTS

Applicants greatly appreciate the courtesies extended by the Examiner to Applicants and its representatives during a personal interview on November 4, 2004. Applicants' representatives and the Examiner discussed the pending rejections and the Scheicher reference during the interview, and the undersigned believes that the interview served to advance prosecution of this case towards allowance of the pending claims.

The Office Action dated September 24, 2004, has been received and carefully considered. In this response, claims 126-138 have been added, the specification and claims 37, 41, 47, 49, 68, 78, 80, 82, 111, 114, 120, and 121 have been amended, and claims 58, 62-67, 77, 93, 99 and 110 have been cancelled without prejudice.¹ Entry of added claims 126-138, and the amendments to the specification and claims 37, 41, 47, 49, 68, 78, 80, 82, 111, 114, 120, and 121, is respectfully requested. Reconsideration of the outstanding objections/rejections in the present application is also respectfully requested based on the following remarks.

I. THE OBJECTION TO THE SUBSTITUTE SPECIFICATION

On page 2 of the Office Action, substitute specification filed on December 4, 2002 was objected to under 37 CFR § 132 as purportedly introducing new matter not supported by the original disclosure. In particular, the Examiner states that "the original disclosure does not

¹ Applicants respectfully disagree with the rejections to which Applicants have responded by canceling or deleting subject matter from the claims and/or specification. Applicants' cancellation or deletion of subject matter, however, is without prejudice and should not be taken as an admission or concession that the subject matter is new matter or anticipated by or obvious in view the cited reference(s). Moreover, Applicants intend to pursue such subject matter in this or co-pending divisional application No. 10/808,553, filed on March 25, 2004.

support the method of milling a vertebral body using the present invention drill head in paragraph [52].” The Examiner further states that “Applicant is required to cancel the new matter in the reply to this Office Action.

Although Applicants disagree with the pending objection, Applicants have deleted the disputed language from Paragraph 52 of the substitute specification. In view of the foregoing, it is respectfully requested that the aforementioned objection to the substitute specification be withdrawn.

II. THE OBJECTION TO THE DRAWINGS

On page 2 of the Office Action, the drawings were objected to under 37 CFR § 1.83(a) as purportedly failing to show every feature of the invention specified in the claims. Specifically, the Office Action states that method claim 62 “is performed with the present invention device in which the device having (sic) a milling surface that has a profile that mates with the profile of the insert.” The Office Action further states that “[i]n fact, the milling surface of the present invention in figs. 1-3 does not mate or look like the profile of the insert in figs. 6 and 7. Therefore, the method of perform invention (sic) must be shown or the feature(s) canceled from the claim(s).”

Although Applicants disagree with the pending objection, Applicants have canceled method claim 62 and its dependent claims. In view of the foregoing, it is respectfully requested that the aforementioned objection to the drawings be withdrawn.

III. THE WRITTEN DESCRIPTION REJECTION OF CLAIMS 36, 37, 39-50, 52-66, 68, 77, 78, 80-85, 87-96, 110, 111 and 114-125

On page 4 of the Office Action, claims 36, 37, 39-50, 52-66, 68, 77, 78, 80-85, 87-96, 110, 111 and 114-125 were rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. Below is each individual rejection followed by Applicants' response:²

1. *Claim 37, "a smooth surface" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have amended claim 37 to remove the term "smooth."

2. *Claims 41, 47, 49, 62, 114, 120 and 121, "the milling surface has a profile which mates with the profile of the insert" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have amended claims 41, 47, 49, 62, 114, 120 and 121 to incorporate the specific language recited in the application, namely: the "profile imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape." *See, e.g.,* Paragraph 25 of the Substitute Specification.

² Applicants respectfully submit that in substantiating many of the written description rejections, the Examiner appears to apply an improper *ipsis verbis* test, rather than the proper reasonable conveyance test. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 925 F.2d 1555 (Fed. Cir. 1991).

3. *Claim 41, "at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the adjacent vertebral body which in use" is not supported in the original specification.*

Although Applicants disagree with the pending objection, Applicants have amended claim 41 to delete the disputed language.

4. *Claim 58, "said bearing surface is smooth" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have canceled claim 58.

5. *Claims 36, 77, 93, 110, "at least two milling surfaces ... and end plate" is not supported in the original specification.*

Although Applicants disagree with the pending objection, Applicants have canceled claims 36, 77, 93, 110.

6. *The steps in method claims 62, 64, 65 and 66 are not supported in the original specification.*

Although Applicants disagree with the pending objection, Applicants have canceled claims 62, 64, 65 and 66.

7. *Claims 68 and 80, "cutters includes first and second milling surfaces" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have amended claims 68 and 80 to delete the disputed language.

8. *Claims 78, 82, 111, "a smooth surface" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have amended claims 78, 82, and 111 to delete the term "smooth."

9. *Claims 98, 112, 113, "at least two milling surfaces" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have canceled claims 98, 112 and 113.

10. *Claim 120, "cutter having a broad milling surface" is not supported in the specification.*

Although Applicants disagree with the pending objection, Applicants have amended claim 120 to delete the term "broad."

In view of the foregoing, it is respectfully requested that the aforementioned indefiniteness rejections be withdrawn.

IV. THE INDEFINITENESS REJECTION OF CLAIM 99

On page 5 of the Office Action, claim 99 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention. The Examiner asserts that claim 99 depends from canceled claim 98. Applicants have canceled claim 99.

In view of the foregoing, it is respectfully requested that the aforementioned indefiniteness rejections be withdrawn.

V. THE ANTICIPATION REJECTION OF CLAIMS 1-3, 5-7, 13-28, 30-50, 52-61, 67-71, 73-85, 87-97, 99-102, 104-111 AND 114-125

On page 5 of the Office Action, claims 1-3, 5-7, 13-28, 30-50, 52-61, 67-71, 73-85, 87-97, 99-102, 104-111 and 114-125 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Scheicher (U.S. Patent No. 4,197,645). This rejection is hereby respectfully traversed.

Applicants respectfully disagree with the pending rejection, and respectfully submit that pending independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, and 121 are structurally distinguishable from the Scheicher reference.

1. The Examiner's Response to Arguments

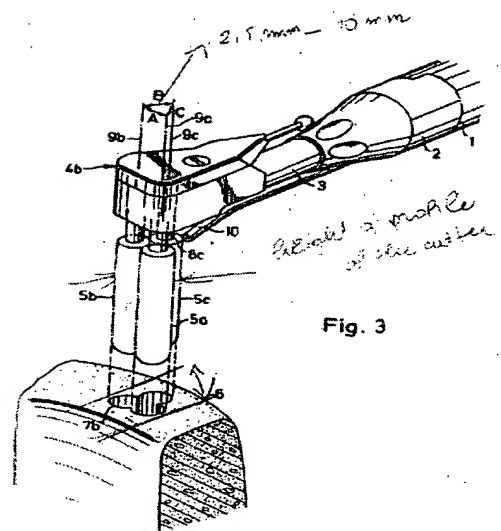
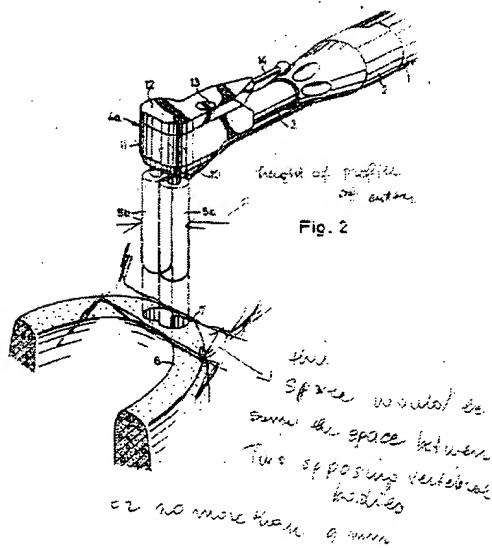
In response to Applicants' arguments in the April 22, 2004 response, the Examiner states that "Scheicher discloses a drilling apparatus having a milling cutter for preparing bone cavities into which an endoprosthesis element can be inserted (see Col. 1, lines 6-10), and the drilling apparatus comprises limitations substantially as claimed; therefore, it is capable of preparing a space having a surface contour in a human spine to receive an insert between adjacent vertebral bodies if one desires to do so."

In particular, the Examiner offers two techniques in which the Scheicher device performs like the claimed devices, namely: (1) by inserting the Scheicher drill heads *lengthwise* into the area between adjacent vertebral bodies (i.e., such that the drill heads are parallel to the surface of the adjacent vertebral bodies--see marked-up Figures 2 and 3 below), and (2) by drilling *through* a vertebral body to get into the area between adjacent vertebral bodies.

The parallel or lengthwise technique is illustrated in marked-up Figures 2 and 3 below.³ Figure 2, for example, shows the Scheicher drill heads entering the area between two adjacent vertebral bodies (depicted as mirror-image brackets “[” [“). Figure 2 indicates -- in the Examiner's handwriting -- that the space between the two brackets “would be the same space between two adjacent vertebral bodies.” Thus, the drill heads are inserted *lengthwise* into the area between the adjacent vertebral bodies such that the sides of the drill heads are parallel to the surfaces of the vertebral bodies. As shown, milling is accomplished along the length of drill heads 5b and 5c.⁴

³ Marked-up Figures 2 and 3 were submitted by the Examiner in support of the September 24, 2004 Office Action to purportedly demonstrate how the Scheicher device performs like the claimed systems and methods.

⁴ In the Declaration of Carlos Gil, submitted as part of Applicants' response to the Final Office Action of August 22, 2003, Applicants' representative, Mr. Gil, stated that this application of the Scheicher device is not practical because the user would not be able to create a predetermined surface contour in an end plate of an adjacent vertebral body. *See* Gil Declaration, ¶ 15. Mr. Gil further stated that upon coming in contact with the surface of the vertebral body, the tendency of the drill head of the Scheicher device would be to roll off, much like a wheel does when coming in contact with a hard, solid surface. *Id.* Mr. Gil stated that this lack of control renders the Scheicher device a useless (and potentially life threatening) instrumentality for performing the type of spinal surgery contemplated by the claimed devices. *Id.*



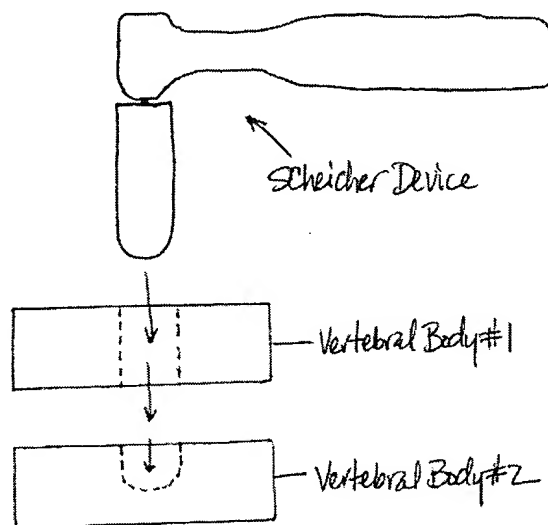
The Examiner indicates that the distance between drill heads 5b and 5c comprises the claimed “height” of the form cutter profile. However, marked-up Figure 3 clearly shows that the distance referred to by the Examiner -- either A, B, or C -- is the distance between the *midpoint* of any two shafts supporting drill heads 5a, 5b or 5c, and *not*, as the Examiner submits, the *width* of any two drill heads side-by-side. Applicants respectfully submit that such a distance would necessarily be greater than any of the distances A, B or C, thus bringing into question whether the drill heads of the Scheicher device: (1) are “capable of imparting a concaval-convex shape to the bone of vertebral bodies” as expressly recited in claim 1, or (2) could fit within the space defined by adjacent vertebral bodies “in order to create a surface contour in one of the adjacent vertebral bodies,” as recited in claim 25, for example.

The second technique proposed by the Examiner was discussed during the interview of November 4, 2004. In this technique, the Scheicher device is used to drill *through* one of the adjacent vertebral bodies (from top to bottom, for example) so that the drill heads may enter the space between adjacent bodies and eventually come into contact with the surface of the *other*

vertebral body. According to the Examiner, it is irrelevant whether a live patient could survive or tolerate such a procedure, or whether such an approach is even possible on a live subject.⁵

The Examiner asserts that the technique would result in the creation of a surface contour in one of the adjacent vertebral bodies, regardless of what happens to the live patient. Below is

Applicants' depiction of the technique:



Applicants respectfully disagree that using the Scheicher device in either of the two techniques would prepare a space in a human spine to receive an insert between adjacent vertebral bodies and/or create a surface contour in one of the adjacent vertebral bodies. In particular, Applicants respectfully submit that each of the pending independent claims is structurally patentable over Scheicher. Each claim is discussed below.

⁵ Of course, if the preamble is given patentable weight, the effect on a live patient would be relevant.

2. Independent Claim 1

Independent claim 1 is structurally patentable over Scheicher because, as shown above, Scheicher does not teach or suggest a form cutter having “a profile . . . of a height capable of being admitted into the space between two opposing vertebral bodies.” Further, as previously argued, Scheicher does not teach or suggest “[a] drill head for preparing the bone of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis device.”⁶

3. Independent Claim 15

Independent claim 15 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] drill head for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis,” and/or (2) a form cutter having a support shaft capable of imparting a concave shape to the bone of vertebral bodies,” and/or (3) wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°.” Applicants respectfully submit that the Examiner’s assertion that approximately 96 degrees could “generally be 90 degrees” is incorrect. Paragraph 32 of the substitute specification clearly distinguishes a right angle (90 degrees) from 96 degrees, stating that the latter is able to “provide a designed orientation to the vertebral bone surface being milled”:

⁶ As set forth in the Response to Final Office Action Dated August 22, 2003, Applicants respectfully submit that the preambles of the pending claims are entitled to limiting effect for at least the following reasons: (1) the preambles contribute to the definition of the claimed systems and methods; (2) the preambles are relevant to and reflect the problems solved by the claimed systems and methods; and (3) the preambles give life and meaning to the claimed systems and methods.

As shown in Figure 2, the form cutter 29 is ***not necessarily oriented at a right angle*** with respect to the drive shaft 54. In the illustrated device, the angle between the support shaft 51 of the form cutter 29 and the device shaft 54 is ***approximately 96° to provide a designed orientation to the vertebral bone surface being milled.***

See, Page 6, ¶ 32 of the Substitute Specification (emphasis added). Applicants respectfully submit that the above excerpt makes it clear that 90 degrees is not the same as 96 degrees.

4. Independent Claim 18

Independent claim 18 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] milling apparatus for preparing surfaces of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis,” (2) “a rotary form cutter having a profile matching the predetermined shape of the endoprosthesis, the rotary form cutter rotatable about a rotation axis,” and/or (3) “wherein the rotary form cutter cuts an imparted shape into the surfaces of the vertebral bodies that matches the predetermined shape of the endoprosthesis by rotation of the rotary form cutter.”

5. Independent Claim 25

Independent claim 25 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies,” and/or (2) “said form cutter has at least one milling surface selected to create a surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.”

6. Independent Claim 41

Independent claim 41 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] form cutter for preparing a space between adjacent vertebral bodies

to receive an insert,” (2) “at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies,” and/or (3) “said at least one milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis shape of the insert to be received between the adjacent vertebral bodies.”

7. Independent Claim 47

Independent claim 47 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert,” (2) “said form cutter has at least one milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means,” and/or (3) “said milling surface is configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the interbody spinal insert.”

8. Independent Claim 49

Independent claim 49 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space to receive an interbody insert within and between the adjacent surfaces of vertebral bodies disposed adjacent a disc space,” (2) “said milling surface has a profile that imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape of the insert to be implanted,” (3) “said milling surface has a configuration adapted to remove bone from the vertebral bodies to prepare

the vertebral bodies to receive the insert,” and/or (4) “said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device.”

9. Independent Claim 67

Independent claim 67 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space in the human spine to receive an insert between adjacent vertebral bodies,” and/or (2) “said form cutter having at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.”

10. Independent Claim 82

Independent claim 82 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space to receive an insert between adjacent vertebral bodies,” and/or (2) “said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.”

11. Independent Claim 97

Independent claim 97 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space in a human spine to receive an insert between adjacent vertebral bodies,” and/or (2) “said form cutter has at least one milling surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies as said form cutter is moved by said drive means.”

12. Independent Claim 114

Independent claim 114 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] form cutter for preparing a space between adjacent vertebral bodies to receive an insert,” (2) “said form cutter having: at least one milling surface and being mountable on a device capable of moving said form cutter to cause said at least one milling surface to create at least one surface having a predetermined contour in an end plate of at least one of the adjacent vertebral bodies,” (3) “said at least one milling surface having a profile that imparts a shape to the bone on the vertebral bodies which mates with a predetermined endoprosthesis surface shape of the insert to be received between the adjacent vertebral bodies,” (4) “said at least one milling surface having a perimeter that is at least in part arcuate,” and/or (5) “said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.”

13. Independent Claim 120

Independent claim 120 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] device for preparing a space in a human spine across a disc space and into the end plates of adjacent vertebral bodies to receive an interbody spinal insert,” (2) “said form cutter having a milling surface selected to remove bone from and create a predetermined surface contour in at least one of the end plates of the adjacent vertebral bodies as said form cutter is moved by said drive means in a plane generally parallel to the predetermined surface contour to be formed in said vertebral body,” and/or (3) “said milling surface being configured to have a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said interbody spinal insert.”

14. Independent Claim 121

Independent claim 121 is structurally patentable over Scheicher because Scheicher does not teach or suggest: (1) “[a] form cutter for preparing a space between adjacent vertebral bodies to receive an insert,” (2) “said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour,” (3) “said at least one top milling surface having a profile that imparts a shape to the bone of the vertebral bodies which mates with a predetermined endoprosthesis surface shape of said insert to be received between said adjacent vertebral bodies,” and (4) “said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.”

Applicants respectfully submit that, at least for the reasons set forth above, independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, and 121 are allowable over Scheicher. Claims 2-14, 16-17, 19-24, 26-40, 42-46, 48, 50-61, 68-81, 83-96, 98-113, and 115-119 are dependent upon independent claim 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, or 121. Thus, since independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, and 121 should be allowable as discussed above, claims 2-14, 16-17, 19-24, 26-40, 42-46, 48, 50-61, 68-81, 83-96, 98-113, and 115-119 should also be allowable at least by virtue of their dependency on independent claims 1, 15, 18, 25, 41, 47, 49, 67, 82, 97, 114, or 121.

In view of the foregoing, it is respectfully requested that the aforementioned anticipation rejection of claims 1-3, 5-7, 13-28, 30-50, 52-61, 67-71, 73-85, 87-97, 99-102, 104-111 and 114-125 be withdrawn.

VI. NEW CLAIMS 126-138

Applicants have added new independent claims 126-138 that distinguish the claimed devices from the Scheicher device, both in structure and operation. Each claim is discussed below.

1. Independent Claims 126-129

Independent claim 126 is substantially the same as claim 25 except that it recites structural features that the Examiner has indicated would further overcome the Scheicher reference. More specifically, claim 126 recite a form cutter that has: (1) a concaval-convex cutting surface⁷, and (2) an undersurface including a beveled gearing surface which cooperates with a pinion gear provided on the distal end of a drive shaft.⁸ Independent claims 127 and 128 are substantially the same as claim 126 except that each includes only one of the structural features proposed by the Examiner as overcoming the Scheicher reference. Claim 127, for example, recites the “undersurface having a beveled gearing surface which cooperates with a pinion gear on a distal end of said drive shaft,” while claim 128 recites the concaval-convex-cutting surface. Claim 129 is substantially the same as claim 127, except that claim 129 recites

⁷ This limitation refers to the form-cutter's ability to form concaval or convex surfaces on adjacent vertebral bodies. The actual shape of the form cutter surface may be as described in the specification. *See, e.g.*, Page 5, ¶ 26 of the Substitute Specification (“To provide a drill head which can prepare the bone of the two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter has a convex milling surface.”)

⁸ Applicants submit that either limitation alone would distinguish the claimed devices from the Scheicher reference. Accordingly, Applicants have added new independent claims 127-129, each of which recites either a concaval-convex cutting surface, *or* an undersurface including a beveled gearing surface which cooperates with a pinion gear provided on the distal end of a drive shaft.

an “undersurface [having] a toothed surface which cooperates with a pinion gear on the distal end of a drive shaft.”

Applicants respectfully submit that new independent claims 126-129 are allowable over the Scheicher reference.

2. Independent Claim 130

Independent claim 130 recites a “*single*” form cutter. Applicants respectfully submit that such a device is distinguishable from the Scheicher device because the latter includes a “*plurality*” of drills or abrading elements. For example, the Scheicher abstract expressly recites “a drilling apparatus for the preparation of bone cavities includes a plurality of drills which are simultaneously driven in opposite direction with the cutting surfaces of each drill overlapping the cutting surfaces of at least one other drill to provide intersecting bone cavities.” *See* Scheicher Patent, Abstract (emphasis added). Scheicher further states that “[t]he drill head according to the invention for attachment of bone drills or cutters . . . is characterized by a mounting for at least two cutters having staggered axes or rotation, and by a driving mechanism for their joint operation.” *See* Scheicher Patent, Col. 2, lines 18-23 (emphasis added).

Scheicher requires a plurality of drills in order to achieve several advantages described in the patent, which include:

The drill head according to the invention *makes it possible to drill simultaneously with several cutters*, whereby with a suitable refinement of the cutters the drill holes can overlap. Since the rotational axes of the individual cutters are positioned accurately with respect to one another, one obtains defined drill holes opening into one another at least in the upper region and which, after removal, if necessary, of webs of bone tissue remaining between them, can form the desired bone cavities intended for insertion of prosthetic elements.

There is a further advantage in that any shifting of the individual cutter is

avoided even when the bone tissue is very soft or brittle at one point, ***since there is at least one other cutter*** to take over the guidance in such a case.

The drill head according to the invention ***makes possible the production of a large number of bone cavities with defined but never-the-less varying shape since in the individual mounting of the drill head cutters of varying length, varying diameter and varying character of head can be used simultaneously in arbitrary combination.*** In this way bone cavities with a defined external contour, but being of varying depth in different regions can be made. ***The overlapping drill holes result in the side walls dumbbell-like in cross section and where the implant is of corresponding shaping this guarantees an optimal and twist-free lodgement for the implant in the jaw,*** similar to that assumed by the natural tooth in the jaw.

See Scheicher Patent, Col. 2, lines 17-52 (emphasis added).

Accordingly, Applicants respectfully submit that Scheicher does not disclose -- and thus cannot anticipate -- a device having a “***single***” form cutter. *See, e.g., Verdegaaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, ***every limitation of the claim.***”); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) (“The ***identical invention*** must be shown in as complete detail as is contained in the ... claim.”); *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986) (“Absence from the reference of ***any*** claimed element negates anticipation.”)

In view of the above, Applicants respectfully submit that new claim 130 is allowable over the Scheicher reference.

3. Independent Claim 131

Independent claim 131 recites a form cutter having a “convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis,” and that “perform milling action in a direction angled away from the direction of head entry into a space

between opposed bodies.” Applicants respectfully submit that claim 131 is distinguishable from Scheicher device because the latter cannot at once: (1) have a concave surface, and (2) mill in a direction angled away from the direction of head entry of the concave milling surface. The methods proposed by the Examiner illustrate the point. For example, if the drill heads of the Scheicher device are inserted *lengthwise* into the space between adjacent bodies, then the milling surface would not be concave. However, if the drill heads go *through* an adjacent vertebral body in order to enter the space between adjacent vertebral bodies, then the milling will not be in a direction angled away from the direction of head entry of the milling surface. Thus, the Scheicher device cannot satisfy both limitations. Accordingly, Applicants respectfully submit that claim 131 is allowable over the Scheicher reference.

4. Independent Claim 132

Independent claim 132 recites a form cutter having “a profile selected to impart a shape in the bone of the vertebral bodies that mates with the endoprosthesis device.” Applicants respectfully submit that the Scheicher reference does not teach or suggest a form cutter having a profile selected to impart a shape in the bone of the vertebral bodies that mates with an endoprosthesis device. In fact, in his declaration Mr. Gil expressly states none of the Scheicher devices includes a form cutter “capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies.” *See*, Gil Declaration, ¶ 11.

5. Independent Claim 133

Independent claim 133 recites “**means for** preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, said space comprising a surface contour in at least one of the adjacent vertebral bodies.” A prior art reference anticipates a means-plus-function element literally if it performs the *identical function* recited in the claim **and** incorporates the corresponding structure disclosed in the specification for performing that function or an equivalent thereof. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc); *Cortland Line Co., Inc. v. Orvis Co., Inc.*, 203 F.3d 1351, 1358 (Fed. Cir. 2000).

Applicants respectfully submit that the Scheicher device neither performs the identical function of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, nor does it disclose the identical structure (or its equivalent) for performing such function. In fact, the pending application mentions that drilling devices like the Scheicher device are incapable of performing like the claimed devices:

In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing vertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, ***currently available drill heads are not always capable of being fit into the narrow space between two opposing vertebral bodies.*** Further, the narrow space between two opposing vertebral bodies cannot always be expanded to allow admittance of currently available drill heads.

Thus, it is an object of the instant invention to provide a ***drill head which can prepare the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis.***

See Page 3, ¶s 11 and 12 of the Substitute Specification.

Even if the Scheicher device was able to perform the claimed function, it does not disclose the identical structure disclosed in the pending application (or one equivalent thereto) for performing such function. The corresponding structure for performing the function of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies is described in the application as follows:

To provide a drill head which can prepare the bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a ***convex milling surface 42***. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body ***with a mating shape complementary to the concaval-convex shape of the endoprosthesis*** which is the subject of co-pending U.S. patent application Ser. No. 08/681,230. As illustrated, this ***tool drill or milling head can mill in a direction angled away from the direction of device entry into the space between the intervertebral bodies***. That edge 44 provides the cutter 29 with the ability to cut in the direction of tool entry into the space between two opposed vertebral bodies.

The form cutter 29 further includes an ***outwardly extending edge 44*** about its perimeter. In addition, the undersurface 47 of the form cutter 29 may be provided with a ***beveled gearing surface 49***. Alternately, the beveled gearing surface 49 may be provided about the undersurface of the upstanding edge.

The form cutter 29 is provided with a ***shaft 51*** extending perpendicularly from its undersurface. The form cutter 29 is supported within the housing 31 by the cooperation between the shaft 51 and the shaft support 37. This arrangement permits the form cutter 29 to be removed from the housing 31 by separating the shaft 51 from the shaft support 37. Thus, when the cutter dulls, it can be replaced with a new cutter to ensure accurate and effective performance of the drill head.

In order to provide a drill head which can fit within the narrow space between two opposing intervertebral bodies in accordance with the invention, the ***maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters***. Providing the bevel gearing surface 49 on the form cutter 29 allows the drill head 20 to be manufactured with such a narrow profile. This ***arrangement eliminates the need for a separate gear and form cutter which would likely add to the height of the drill head***. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing intervertebral bodies in the cervical spine of a patient.

See ¶ s 20-23 of the Original Application (emphasis added).

Applicants respectfully submit that the Scheicher reference does not disclose a form cutter that is capable of preparing a space in a human spine to receive the endoprosthesis device between adjacent vertebral bodies, nor does it disclose a form cutter having the identical structure described above (or one equivalent thereto).

In view of the above, Applicants respectfully submit that new independent claim 133 is allowable over the Scheicher reference.

6. Independent Claim 134

Independent claim 134 recites a form cutter that has “at least one *vertebral body surface contour* milling surface.” Applicants respectfully submit that the Scheicher device does not include a vertebral body surface contour milling surface. Accordingly, Applicants respectfully submit that new independent claim 134 is allowable over the Scheicher reference.

7. Independent Claims 135-138

Independent claim 135 recites that the profile of the form cutter: (1) “is of a height capable of being admitted into the space between two opposing vertebral bodies,” and (2) “rotate[s] about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies.” Applicants respectfully submit that such a device is distinguishable from the Scheicher device. Scheicher, for example, does not disclose a device having a form cutter that both: (1) rotates about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies, and (2) is of a height capable of being admitted into the space between two opposing vertebral bodies. Thus, if the

Scheicher device is turned sideways to mill the surface of a vertebral body along the length of a drill head, it would not then “rotate about a shaft extending perpendicularly from its undersurface and the space between said opposing vertebral bodies,” as expressly required by claim 135. Similarly, if the other technique is used -- i.e., drilling *through* one of the adjacent vertebral bodies -- the height of the form cutter’s profile would not be such that it is capable of being admitted into the space between two opposing vertebral bodies. Moreover, the head of the form cutter would not be performing a “milling action in a direction *angled away* from the direction of head entry,” as required by claim 135.

Independent claim 136 recites that the form cutter profile has at least one milling surface that is “positioned to mill in a direction perpendicular to said elongated shaft portion.” Applicants respectfully submit that the Scheicher devices do not include a milling surface that is positioned to mill in a direction perpendicular to an elongated shaft portion.

Independent claim 137 recites that the “surface contour [is] generally parallel to said elongated shaft portion.” Applicants respectfully submit that the Scheicher devices do not create surface contours that are generally parallel to the elongated shaft portion.

Independent claim 138 recites that the “at least one milling surface [is] entirely within an area formed by the adjacent vertebral bodies during milling.” Applicants respectfully submit that the Scheicher devices do not teach or suggest “milling surfaces” that are entirely within the area formed by adjacent vertebral bodies during milling.”

In view of the above, Applicants respectfully submit that claims 135-138 are allowable over the Scheicher reference.

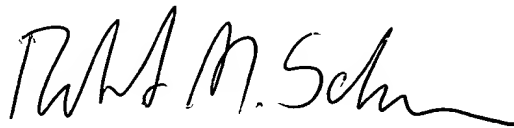
VIII. CONCLUSION

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

HUNTON & WILLIAMS LLP

A handwritten signature in dark ink, appearing to read "R.M. Schulman", written over a horizontal line.

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